

COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 4487-02
Bill No.: HCS for HB 1387
Subject: Children and Minors; Health Care; Health and Senior Services, Department of;
Medical Procedures and Personnel
Type: Original
Date: February 9, 2016

Bill Summary: This proposal expands the newborn screening requirements to include severe combined immunodeficiency (SCID).

FISCAL SUMMARY

ESTIMATED NET EFFECT ON GENERAL REVENUE FUND			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
Total Estimated Net Effect on General Revenue	\$0	\$0	\$0

ESTIMATED NET EFFECT ON OTHER STATE FUNDS			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
MoPHS	Could exceed \$54,761	Could exceed \$60,645	Could exceed \$48,214
Total Estimated Net Effect on <u>Other</u> State Funds	Could exceed \$54,761	Could exceed \$60,645	Could exceed \$48,214

Numbers within parentheses: () indicate costs or losses.
This fiscal note contains 10 pages.

ESTIMATED NET EFFECT ON FEDERAL FUNDS			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
Federal*	\$0	\$0	\$0
Total Estimated Net Effect on <u>All</u> Federal Funds	\$0	\$0	\$0

* Income and transfer-out nets to \$0.

ESTIMATED NET EFFECT ON FULL TIME EQUIVALENT (FTE)			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
MoPHS	2	2	2
Total Estimated Net Effect on FTE	2	2	2

☐ Estimated Net Effect (expenditures or reduced revenues) expected to exceed \$100,000 in any of the three fiscal years after implementation of the act.

ESTIMATED NET EFFECT ON LOCAL FUNDS			
FUND AFFECTED	FY 2017	FY 2018	FY 2019
Local Government	\$0	\$0	\$0

FISCAL ANALYSIS

ASSUMPTION

Officials from the **Department of Health and Senior Services (DHSS)** provide the following assumptions:

Division of Community and Public Health

Based on information from states that have implemented severe combined immunodeficiency (SCID) screening, it is predicted that by adding SCID to the newborn screening panel, Missouri would have a total of 120 - 267 abnormal screenings annually that would need to be followed up on for a repeat screen or to coordinate with the treatment centers for confirmation of the disorders. Thus, it is assumed that the tracking and follow-up of SCID would exceed the current capacity of the newborn screening program.

Due to the nature of SCID, it would not be appropriate to add funding to the existing genetic contracts because newborns referred for follow-up after an abnormal SCID newborn screen would not be seen or followed in the genetic clinics. These newborns would be seen by immunologists and, if necessary, transplant teams. Therefore, the newborn screening program would require one (1) Public Health Senior Nurse (\$49,788 annually) to conduct and coordinate all follow-up activities for SCID newborn screening.

The Public Health Senior Nurse responsibilities would include:

- Coordinating and facilitating a SCID Newborn Screening Task Force to advise the Newborn Screening program in the implementation of adding SCID to the newborn screening panel;
- Coordinating directly with the primary care provider, the family, and the specialists to confirm or rule out the disorder and assure treatment as appropriate;
- Developing any necessary parent educational materials on SCID;
- Revising the newborn screening pamphlet to include information on SCID;
- Collaborating with the Missouri State Public Health Laboratory to develop procedures for calling out high risk SCID newborn screening results;
- Collaborating with physicians, nurses, and other medical professionals to ensure all newborns with a high risk SCID newborn screen are followed-up appropriately including all necessary evaluations and tests to confirm or rule out a disorder;
- Ensuring all confirmatory results and diagnoses are received and documented in order to close out the cases;
- Responding to calls from families that receive letters regarding SCID or are calling to find out more about newborn screening;

ASSUMPTION (continued)

- Continually evaluate and monitor SCID newborn screening to ensure policies and procedures are in alignment with best practice and evidence-based standards of care; and
- Any additional tasks or duties related to SCID newborn screening.

The newborn screening pamphlet would need to be revised to include information on SCID. This would be a one-time cost of \$6,000 to revise and reprint the pamphlet (100,000 pamphlets X \$.06 each = \$6,000).

State Public Health Laboratory (SPHL):

The State Public Health Laboratory (SPHL) will need to hire one (1) additional FTE Senior Public Health Laboratory Scientist (\$41,940 annually) to be responsible for the oversight, analytical testing, interpreting of results, and reporting of approximately 375 newborn screening samples per working day for the SCID testing section.

The job description for Senior Public Health Laboratory Scientist includes:

- Opening daily samples received and assessing for quality and suitability;
- Processing samples into split samples for the SCID testing platforms;
- Comprising work lists, making necessary solutions, and performing instrument preparations;
- Performing the molecular amplification and detection procedures for the presence of T-Cell Receptor Excision Circles (TRECs) to detect SCID;
- Reviewing and interpreting test results, and conducting necessary re-testing of abnormal results;
- Assessing the risk of abnormal results and contacting appropriate genetic referral center for confirmation and follow-up testing.
- Reviewing and approval of daily instrument controls for accuracy;
- Monitoring QC results for shifts and trends, and performing corrective and preventive actions;
- Oversight of instrument performance, maintenance, and troubleshooting;
- Conducting and oversight of regular proficiency testing to assure accuracy and proficiency certifications;
- Training and cross-training new scientists to be proficient in the SCID section;
- Ordering testing reagents and maintaining good inventory of items necessary for continuation of operations; and,
- Compiling monthly, annual, and as-needed reports for the newborn screening manager.

ASSUMPTION (continued)

All laboratory equipment and expense costs associated with SCID testing are based upon vendor quotes for technology currently available. The DHSS assumes the proposal will have a cost to the MoPHS Fund of \$657,801 for FY 2017; \$761,285 for FY 2018 and \$777,560 for FY 2019.

DHSS currently has the authority to set the fee per 191.331, RSMo. It will be necessary to raise the newborn screening fee to add SCID testing. These fund would be deposited into the Missouri Public Health Services (MoPHS) Fund. DHSS estimates that the fee will increase by \$9.00 when testing is begun.

Based on previous years, it is estimated the DHSS will perform 95,640 screens annually - 80,640 will be billed to the submitters (hospitals) and approximately 15,000 will be submitted to Medicaid. $15,000 \times \$9$ (can only claim Medicaid for the lab portion) $\times 60\%$ (Federal Medical Assistance Percentage rate) = \$81,000; $80,640 \times \$9 = \$725,760$; total annual income \$806,760 (\$81,000 + \$725,760).

The net estimated fiscal impact to the MoPHS Fund is expected to be \$148,959 for FY 2017; \$45,475 for FY 2018; and \$29,200 for FY 2019.

Oversight assumes the DHSS does not need additional space for 2 FTE.

Oversight assumes the provisions of this proposal will take effect on January 1, 2017 when the state employee health insurance plan year goes into effect. In addition, Oversight assumes, based on the Department of Social Services, MO HealthNet response a 3.0% growth rate in Medicaid reimbursements for newborn screening expenses.

Oversight notes the provisions of HCS for HB 1387 contains an emergency clause. Due to the effective date in the proposal, the emergency clause will not affect the fiscal impact of this proposal.

Officials from the **Department of Social Services (DSS), MO HealthNet Division (MHD)** state by January 1, 2017, the Department of Health and Senior Services (DHSS) shall, subject to appropriations, expand the newborn screening requirements in section 191.331 to include severe combined immunodeficiency (SCID), also known as bubble boy disease.

Currently, newborn screenings are reimbursed by the MHD for the federal portion only. The general revenue portion is included in the DHSS budget.

In State Fiscal Year (SFY) 2014, the MHD was billed for approximately 15,000 newborn screenings by the State Health Lab. For this calculation, it is assumed the same number of screenings would be billed in SFY 2017 as billed in SFY 2014.

ASSUMPTION (continued)

At this time the rate for the additional newborn screenings is unknown. Using DHSS' estimates that the rate will be \$9.00, the result would be \$135,000 (\$9 increase X 15,000 newborn screenings).

Fiscal Impact: Unknown, but at least:

FY 2017 (calculated for 6 months): Total Federal Funds \$42,679;
FY 2017 (3.0% trend factor): Total Federal Funds \$87,919; and,
FY 2018 (3.0% trend factor): Total Federal Funds \$90,556.

There is no fiscal impact on the Division of Legal Services.

Officials from the **University of Missouri Health Care** state the proposed legislation has been reviewed and it has been determined that, as written, it should not result in a net loss in excess of \$100,000 based on the proposed revenue offset.

Oversight assumes this is an amount which the University assumes is an absorbable loss within current resource levels.

Officials from the **Hermann Area District Hospital** stated that they have not provided obstetric services since 2000 and as a result, no impact statement was provided.

Officials from the **Joint Committee on Administrative Rules (JCAR)** state the legislation is not anticipated to cause a fiscal impact to JCAR beyond its current appropriation.

Officials from the **Missouri Consolidated Health Care Plan** and the **Missouri Department of Conservation** each assume the proposal would not fiscally impact their respective agencies.

Officials from the **Department of Public Safety, Missouri State Highway Patrol** defer to the Missouri Department of Transportation (MoDOT), Employee Benefits Section for response on behalf of the Highway Patrol. Please see MoDOT's fiscal note response for the potential fiscal impact of this proposal.

In response to the previous version of this proposal, officials from the **Missouri Department of Transportation** assumed the proposal would not fiscally impact their agency.

In response to the previous version of this proposal, officials from the **Office of the Secretary of State (SOS)** stated many bills considered by the General Assembly include provisions allowing or requiring agencies to submit rules and regulations to implement the act. The SOS is provided

ASSUMPTION (continued)

with core funding to handle a certain amount of normal activity resulting from each year's legislative session. The fiscal impact for this fiscal note to the SOS for Administrative Rules is less than \$2,500. The SOS recognizes that this is a small amount and does not expect that additional funding would be required to meet these costs. However, the SOS also recognizes that many such bills may be passed by the General Assembly in a given year and that collectively the costs may be in excess of what the office can sustain with the core budget. Therefore, the SOS reserves the right to request funding for the cost of supporting administrative rules requirements should the need arise based on a review of the finally approved bills signed by the governor.

Oversight assumes the SOS could absorb the costs of printing and distributing regulations related to this proposal. If multiple bills pass which require the printing and distribution of regulations at substantial costs, the SOS could request funding through the appropriation process.

Officials from the following **hospitals**: Barton County Memorial Hospital, Bates County Memorial Hospital, Cedar County Memorial Hospital, Cooper County Hospital, Excelsior Springs Medical Center, Putnam County Memorial Hospital and Washington County Memorial Hospital did not respond to **Oversight's** request for a statement of fiscal impact.

<u>FISCAL IMPACT - State Government</u>	FY 2017 (6 Mo.)	FY 2018	FY 2019
MoPHS FUND (§191.332)			
<u>Income - DHSS</u>			
Increase in infant screening fees	\$362,880	\$725,760	\$725,760
<u>Transfer-in from DSS Federal Fund</u>			
Reimbursement for screening costs	<u>At least \$42,679</u>	<u>At least \$87,919</u>	<u>At least \$91,556</u>
Total <u>Income and Transfers-in - DHSS</u>	<u>At least</u> <u>\$405,559</u>	<u>At least</u> <u>\$813,679</u>	<u>At least</u> <u>\$817,316</u>
<u>Costs - DHSS</u>			
Personal service	(\$41,715)	(\$92,645)	(\$93,572)
Fringe benefits	(\$21,489)	(\$45,495)	(\$45,748)
Equipment and expense	<u>(\$287,594)</u>	<u>(\$614,894)</u>	<u>(\$629,782)</u>
Total <u>Costs - DHSS</u>	<u>(\$350,798)</u>	<u>(\$753,034)</u>	<u>(\$769,102)</u>
FTE Change - DHSS	2 FTE	2 FTE	2 FTE
ESTIMATED NET EFFECT ON THE MoPHS FUND	<u>Could exceed</u> <u>\$54,761</u>	<u>Could exceed</u> <u>\$60,645</u>	<u>Could exceed</u> <u>\$48,214</u>
Estimated Net FTE Change on the MoPHS Fund	2 FTE	2 FTE	2 FTE
FEDERAL FUNDS (§191.332)			
<u>Income - DSS</u>			
Increase in reimbursement for SCID newborn screening expenses	At least \$42,679	At least \$87,919	At least \$90,556
<u>Transfer-out - DSS</u>			
Transfer-out to DHSS MoPHS Fund for SCID newborn screening expenses	<u>(At least)</u> <u>\$42,679</u>	<u>(At least)</u> <u>\$87,919</u>	<u>(At least)</u> <u>\$90,556</u>
ESTIMATED NET EFFECT ON FEDERAL FUNDS	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>

FISCAL IMPACT - Local Government

FY 2017
(6 Mo.)

FY 2018

FY 2019

\$0

\$0

\$0

FISCAL IMPACT - Small Business

Small business birthing centers, midwives and any other entities that purchase newborn screening collection forms would have to pay an additional fee. However, this cost may be recovered by the fees charged. There would also be additional administrative costs.

FISCAL DESCRIPTION

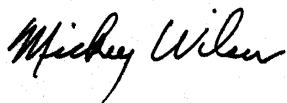
This bill requires the Department of Health and Senior Services, subject to appropriations, to add severe combined immunodeficiency (SCID), also known as the bubble boy disease to the list of newborn screening requirements.

This proposal contains an emergency clause.

This legislation is not federally mandated, would not duplicate any other program and would not require additional capital improvements or rental space.

SOURCES OF INFORMATION

Department of Health and Senior Services
Department of Public Safety -
 Missouri State Highway Patrol
Department of Social Services
Joint Committee on Administrative Rules
Missouri Consolidated Health Care Plan
Missouri Department of Conservation
Missouri Department of Transportation
Office of Secretary of State
University of Missouri
Hermann Area District Hospital



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Mickey Wilson, CPA
Director
February 9, 2016

Ross Strobe
Assistant Director
February 9, 2016